UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., CIVIL ACTION NO. 06-11337-PBS	)	

MEMORANDUM BY THE UNITED STATES RELATING TO THE *IN CAMERA* SUBMISSION OF DOCUMENTS FOLLOWING THE HEARING ON JULY 24, 2008

The United States files this memorandum concurrently with its submission of twelve documents for *in camera* review by the Court.

Background - The Court's July 24 Hearing

This submission follows a hearing on July 24, 2008 relating to the request by Abbott Laboratories, Inc. (Abbott), that the Court certify its rulings on the Government's invocation of the deliberative process privilege for interlocutory appeal (Dkt. 5256 ("Certification Req."). At the outset of the July hearing, the Court inquired about the Government's position with respect to the Court's findings regarding a "30 percent yardstick" relating to drug prices and whether, in this case, the Government is "claiming as damages everything that's different from actual acquisition cost" and whether the Government's damages analysis is "building in the 30 percent yardstick?" The Court explained that if the Government were "not conceding the 30 percent yardstick . . . [the Government's] allowed to do that . . . [b]ut [defendants are] allowed discovery to understand it better." The Court further directed that it would review, *in camera*, any

documents which the Government had withheld from production based on the deliberative process privilege which relate to "cross-subsidization" or "mega spreads" for infusion and inhalation drugs. The Court directed, however, that the Government should refrain from submitting draft versions of reports by the Office of Inspector General for DHHS (OIG).

The Government has already filed a written response to the Court's question about the 30 percent yardstick and explained that the Government's damages estimate has, in the Court's words, at least a 25 percent yardstick "built into it." As for the documents that are now being submitted to the Court *in camera*, none of them have probative value with respect to the claims and defenses at issue in this case. The Court should deny both Abbott's requests for their compelled production and to be allowed to an interlocutory appeal of the Court's rulings on the deliberative process privilege.

The Government's Document Production and the Material Reviewed for Potential *In Camera* Submission

To date the Government has produced well in excess of 350,000 pages of material in this matter – either with its Rule 26 initial disclosures or in response to discovery requests from the three defendants.[1] Abbott, for its part, served 142 document requests on the United States. The three primary sources for the documents produced by the Government have been the Centers for Medicare and Medicaid Services (CMS), the private contractors (known as "Carriers") which are involved in the administration of the Medicare Part B benefit, and OIG. Material withheld from production by the United States falls into three categories: (1) material from the above three sources which the Government reviewed during its document productions and which has been

[1] This number does not include documents made available for inspection by defendants or any of the Government's production of claims and payment data.

described on a document-specific basis on the Government's privilege logs;[2] (2) documents from CMS's Office of Legislation; and (3) Rulemaking Support Files maintained in connection with notices of proposed and final rules published by CMS (for the second two sources, the Government has not been required to create document-by-document privilege logs).

Abbott has previously moved to compel production from all three sources. With respect to documents from the privilege log, Magistrate Judge Bowler initially ordered the Government to release a narrow class of certain defendant-specific documents from the log. The District Court amended that order and, instead, required the Government to submit, *in camara* to the Magistrate Judge, "documents which relate to its knowledge of a 'spread' for Abbott's drugs at issue in this litigation or its knowledge of Abbott's 'marketing the spread' for any of its drugs." *See* Order of Nov. 9, 2007 (Dkt. 4885). Abbott later moved to compel the production of material from the Office of Legislation and CMS's Rulemaking Support Files. The District Court for the most part upheld the Magistrate Judge's decision denying Abbott's motion but also issued an instruction similar to that given on November 9, directing the Government to submit for *in camera* review documents from the Office of Legislation and Rulemaking Support Files which related to the spread for the drugs at issue in this litigation or defendant's marketing of the spread. *See* Docket Order of Mar. 14, 2008. The Government filed an initial *in camera* submission on December 4, 2007 (Dkt. 4920), and a second supplemental submission on June 3, 2008 (Dkt. 5353).

[2] The Government's privilege logs were produced on a rolling basis beginning in February 2007, with service of the final log in April 2008.

Following the July 24, 2008 hearing, the Government conducted a comprehensive re-review of the documents withheld from production in each of the three categories noted above. First, the Government reviewed all the entries on the privilege logs produced by the United States and re-reviewed documents from the logs which fell within the criteria stated by the Court on July 24. Consistent with the Court's instructions, the Government omitted from this review drafts of OIG reports. Second, the Government also reviewed documents from the Office of Legislation - material which had already been subject to close review in connection with Abbott's earlier attempts to compel production from this source.

With respect to the third source – the Rule Making Support Files – the Government's review focused on material related to regulations targeted by Abbott's discovery requests. An Abbott RFP, in pertinent part, had requested documents relating to any proposed or final federal regulation concerning the payment for drugs under Medicare or Medicaid, including nine regulations listed on a schedule attached to the RFPs (and appended to this brief as Exhibit 1). The nine regulations span the period from 1965 through 2003.

Over the last seven weeks, the Government obtained the Rulemaking Support Files for the four regulations on Abbott's list which actually took effect during the claims period at issue in the case against Abbott (items four through seven on Abbott's schedule).[3] With respect to the first three regulations on Abbott's list - regulations published between 1969 and 1975, CMS has transferred custody of the rulemaking material to the National Archives. Those files have not

[3] The Government reviewed files relating to a Notice of Proposed Rulemaking at 52 Fed. Reg. 28,648 (July 31, 1987); a Notice of Proposed Rulemaking at 63 Fed. Reg. 30,818 (June 5, 98); a Notice of Final Rulemaking at 63 Fed. Reg. 58,814 (Nov. 2, 1998), a Notice of Proposed Rulemaking at 63 Fed. Reg. 47,552 (Sept. 8, 1998); and a Notice of Final Rulemaking at 65 Fed. Reg. 8,434 (April 7, 2000).

been retrieved by the Department of Justice and the Government should not be required to do so given the age of the material and in light of the arguments set out below. Due to delays obtaining archived material relating to the eighth and ninth regulations on Abbott's schedule, the Government was unable to complete its review of those files by the date of this filing. The United States proposes that it file a supplemental submission, if necessary, after those files have been reviewed by counsel for the Government.

The Documents Submitted for *In Camera* Review

Based upon the review of the material described above, the Government has submitted twelve documents to the Court for *in camera* inspection. None of the documents indicate that CMS approved of the mega-spreads at issue for the drugs upon which the United States has sued, much less communicated any such approval to a defendant.

Argument

After concluding that the deliberative process privilege has been properly invoked, as the Court has done here, a court must balance the public interest in protection of the deliberative process against the particularized need for the information as evidence in the case before it. *See Comm. for Nuclear Responsibility, Inc. v. Seaborg,* 463 F.2d 788, 791 (D.C. Cir. 1971); *Scott v. PPG Indus., Inc.*, 142 F.R.D. 291, 294 (N.D. W. Va. 1992). To compel disclosure, the requesting party must make "a showing of necessity sufficient to outweigh the adverse effects the production would engender." *Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena,* 40 F.R.D. 318, 327-29 (D.D.C. 1966), *aff'd*, 384 F.2d 979 (D.C. Cir. 1967). When balancing the Government's interest in protecting its deliberative processes against an opponent's need for the evidence, the following factors should be considered:

> (i) the relevance of the evidence sought to be protected; (ii) the availability of other evidence; (iii) the 'seriousness' of the litigation and the issues involved; (iv) the role of the government in the litigation; and (v) the possibility of future timidity by government employees who will be forced to recognize that their secrets are violable.

In re Franklin Nat'l Bank Sec. Litig., 478 F.Supp 577, 583 (E.D.N.Y. 1979) (citations omitted).

An application of these factors to the documents submitted by the Government weighs heavily in favor of nondisclosure – both (a) as a general matter in light of the governing legal principles and the Court's rulings on seminal issues in this case, and (b) when applied to the particular documents which are being submitted to the Court.

Factor One - Relevance of the Protected Information

a. The "30 Percent Expectations Yardstick"

With respect to the Court's inquiry regarding the Government's position on the "30 percent yard stick" between drug companies' reported AWPs and their actual sales prices, it appears that the Court's inquiry may have been prompted by an assertion in Abbott's request for certification of interlocutory appeal, to the effect that:

> At bottom, the United States seeks in this case to recover *the full extent of* the "spread," or "margin," between the Medicare and Medicaid payments it made for four families of Abbott generic drugs..."

Certification Req. at 1 (emphasis supplied). If Abbott is asserting that the United States seeks to recover the full extent of the spread, *inclusive of the first 20 to 30 percent* covered by the Court's yardstick, Abbott is demonstrably *wrong*. The expert report served by the United States on Abbott in June 2008 made clear that the United States was excluding the first 25 percent of Abbott's spread from its damages estimate. Moreover, at no time, whether in formal discovery

responses, written correspondence, or informal communications with Abbott's counsel, has the United States ever advanced the position stated in Abbott's brief.

As reported to the Court following the July 24 hearing, the United States' damages estimate for the drugs in the complaint excluded the first 25 percent of Abbott's spread from that calculation (by adding a 25% markup to Abbott's actual market prices when determining a "substitute AWP"). *See* Dkt. 5492. The Government also explained that it will follow the same methodology in the Dey and Roxane cases, thus giving all defendants the benefit of an imputed formulaic spread of 25%. In short, the United States's damages calculations take into account the typical differential between a manufacturer's reported prices and AWP - or what the Court (and the Court's expert) has referred to as the "expectations yardstick."[4] Moreover, the United States has sued Abbott only on mega-spread drugs – not for any drugs with spreads within the "expectations yardstick." *See* Exhibit One to the Complaint of the United States (showing spreads for Abbott drugs ranging from 275% to 1784% -- ***with the majority of the spreads exceeding 1000%***) (Dkt. 4281).

Abbott also attempts to cloak its conduct within the mantle of some purported governmental interest in using spread to "cross subsidize" the costs providers might incur when dispensing drugs. At the close of the Track One trial, however, the Court indicated that

> there was no evidence about the extent of a shortfall in the costs of administration of the drugs in question in this litigation. Moreover, there was no evidence that any margin over the 20 to 25 percent industry-wide formula was needed to compensate doctors for their costs of administration for these drugs and risks like spoilage. Significantly, the pharmaceutical companies marketed the spread by demonstrating to the doctor that he would make a profit on the drug, not by demonstrating that the drug would cover costs of administration or other risks.

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[4] *In Re Average Wholesale Price Litig.,* 491 F. Supp. 2d 20, 437-38 (D. Mass. 2007)

In Re Average Wholesale Price Litig., 491 F. Supp. 2d 20, 40 (D. Mass. 2007). The state of the evidence is no different with respect to the three defendants sued by the United States, Abbott, Dey and Roxane. The "cross-subsidization" issue is a red herring given the complete lack of any evidence, or even a claim, that Abbott, for example, set its mega-spreads by estimating a purported shortfall that physicians or pharmacies would otherwise encounter in connection with drugs administered to Medicare and Medicaid beneficiaries. Indeed, all the evidence is to the contrary.

In sum, to the extent that the Court's instructions to the United States on July 24 regarding a further *in camera* submission were premised on the possibility that documents responsive to the Court's specifications might be relevant defendants' liability for spreads within the 30 percent yard stick, or might be relevant to how the damages caused by defendants should be measured, the United States submits that such is not the case given the particular mega-spread drugs upon which the United States has sued and the method used by the Government to estimate damages sustained with respect to claims for those drugs.

b. Abbott's Purported Need for the Documents

In addition to Abbott's incorrect assertion that the Government is claiming the "full extent" of Abbott's spread as damages in this case, Abbott has repeatedly demanded access to privileged documents by arguing that such material would show "why the Government consciously decided to continue to use a payment methodology that it knew resulted in 'overpayments' for prescription drugs. Certification Req. at 7.[5] In its deliberative process briefs,

[5] *See also* Abbott's deliberative process briefs at Dkt. 5115 at 2 (arguing Abbott needed to find out "why .... CMS [chose] to permit the Medicare and Medicaid programs to continue paying on AWP when officials knew that there was a 'spread' between AWP and Acquisition

Abbott has been candid that a central purpose behind its demand for privileged material is so that it can re-litigate the core issue decided by the Court in its November 2006 summary judgment ruling construing the meaning of the term "AWP." According to Abbott, "it has now become clear that the Court's ruling on AWP was based on a misleading brief from the Government and an incomplete factual record." *See* Dkt. 4890 at 3-4. This Court, however, construed the term "AWP" based on its plain language, not on the basis of what any agency employee personally thought about the term. To the extent the Court considered other canons of regulatory and statutory construction, the decision adhered to the principles set out by the First Circuit in *United States v. Lachman,* 387 F.3d 42, 54 (1st Cir. 2004), and looked only to the official record to analyze regulatory intent. The Court has already resolved the key issue of interest to Abbott by virtue of its November 2006 Order in which it construed the term AWP pursuant to its plain language. Moreover, even if there were an open issue regarding Governmental intent and this pricing term, it would be resolved by reference to public policy pronouncements by CMS.

To date, both the Magistrate Judge and this Court have found, without exception, that Abbott's arguments for access to privileged material do not present sufficient grounds for

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costs?"); Dkt. 4474 at 10 (arguing Abbott needed discovery on the issue of "*Why* didn't the Government change the way Medicare and Medicaid reimbursed drugs when CMS *knew* the published prices bore little resemblance to the decreasing market prices for those drugs")(emphasis in original); Dkt. 4698 at 13 (arguing privilege objections would prevent testimony regarding "the real reasons the Government continued to use published prices, knowing full well that they far exceeded actual acquisition costs"); Dkt. 4791 at 2 (arguing sought-after discovery would show "why Medicare and Medicaid continued to use AWP even though CMS knew the benchmark price exceeded providers' acquisition costs for prescription drugs"); Dkt. 4890 at 1-4 (arguing for discovery as to "why the Government acquiesced in or chose to continue using a payment system based upon published AWP"); Dkt. 5049 at 5 (argument for documents showing "*why* CMS used an AWP-based system [and] the pros and cons of alternative methodologies that were considered and rejected")(emphasis in original).

overruling the Government's privilege objections. For example, a February 1, 2008 decision of the Magistrate Judge denied Abbott's motion to compel legislative and regulatory material from CMS. In resolving Abbott's motion, the Magistrate Judge held that the burden of production outweighed the benefit of the information. Abbott's objections to this holding were then denied by this Court in a docket order entered on March 14, 2008.

As the Government has explained in various briefs filed in opposition to Abbott's repeated attempts to compel production of privileged material, Abbott's purported need for the material in question rests on several flawed premises. First, Abbott's assertion that the Government did nothing in response to abusive AWP reporting practices is obviously incorrect in light of the statutory changes effected by the Medicare Modernization Act of 2003, as well as the other efforts undertaken by CMS prior to the passage of the MMA to respond to the problem of AWP inflation. *See In Re Average Wholesale Price Litig.,* 491 F. Supp. 2d at 41-44. Second, the Government's continued reliance on an AWP-based payment system that turned out to be susceptible to costly abuse cannot insulate a drug manufacturer from liability for its role in abusing the system. *Id.* at 94.

Moreover, the Government has also demonstrated why the issue which Abbott has so relentlessly pursued is irrelevant in light of decisions by the Court in this MDL (*see In Re Average Wholesale Price Litig.,* 460 F. Supp. 2d 277, 278 (D. Mass. 2006) (construing AWP as a matter of law)) and based on First Circuit precedent which is directly on point (*United States v. Lachman*, As noted above, in *Lachman*, the Court of Appeals held that any interpretive issue relating to a regulation is resolved through reference to the official *public* record. 387 F.3d at 54. Any issue about Governmental intent, whether it be in changing a policy or refraining from a

policy change, is not resolved by reference to the predecisional deliberations of individuals. As the First Circuit made clear, "non-public or informal understandings of agency officials concerning the meaning of a regulation are . . . not relevant." *Id.* The "non-public understanding[s] [of individual government officials] of the regulation do not remotely satisfy the requirements of formality and public accessibility" and are not entitled to any deference. *Id.* *See also United States ex rel. Wright v. Agip, et al.*, No. 03-Cv-00264 at 7-9 (E.D. Tex. June 29, 2007) (denying motion to compel deposition of Government personnel regarding their understanding of regulations, and holding that "personal opinions of agency employees that were never communicated to a Defendant are simply irrelevant to either issues of falsity or knowledge").

Furthermore, the Court already has addressed the issue of why the Government continued to use AWP to set drug payments despite evidence that AWPs reported by some manufacturers for certain drugs were not reflective of market prices. The Court's June 2007 Findings and Conclusions describe the "opaque" nature of pharmaceutical pricing information for physician-administered drugs such as those sold by Abbott (*In Re Average Wholesale Price Litig.,* 491 F. Supp. 2d at 40), and the difficulties in devising non-AWP payment systems (*id.* at 91) despite the Government's emerging recognition of the vulnerability of its payment systems and the need to develop an alternative "pragmatic pricing methodology to handle millions of annual drug transactions" (*id.* at 40-41, 91). The Court also described the Government's efforts to grapple with the problem created by the abusive practices of certain drug manufacturers. *Id.* at 41-46. The Court's use of analogy to describe the challenge faced by the entities paying beneficiary drug

claims ("shifting the pricing paradigm from AWP to another approach is like turning the RMS Queen Elizabeth") was particularly apt. *Id.* at 91.

As this Court has recognized, the defense which *may* be viable in an FCA case relates to a *defendant's* knowledge regarding the falsity of its statements or claims. Under the FCA, to negate scienter, defendants must show that (1) they fully informed the Government of the conduct at issue, and (2) the Government *approved* of the conduct at issue. *In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 861178, at *7 (D. Mass. March 22, 2007) (denying motion to dismiss California False Claims Act claim, noting that government approval of the particulars is necessary to negate scienter)*; see also United States ex rel. Tyson v. Amerigroup,* 2007 WL 781729, at *20 (N.D. Ill. March 13, 2007) (proper test is whether the government knew and approved the particulars of defendant's conduct.) The mere fact that a particular Government employee knew certain facts about drug payment is not, in and of itself, relevant, because "government knowledge" is not a defense under the FCA; *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) ("that the relevant government officials knew of the falsity is not in and of itself a defense.").

Given that the documents provided to the Court *in camera* were not released outside of the agency during the time frame at issue in this litigation, none of them could have had any impact on defendants' scienter. Simply put, defendants cannot reasonably claim that their views about the legality of their price reporting practices were somehow influenced by documents that they have never seen.

Factor Two - Availability of Other Evidence

Even if the issue of regulatory intent and AWP had not been resolved by the Court, any open issue on this front would be analyzed by reference to the official public record. CMS's rulemaking with respect to pharmaceutical payments has been transparent. The agency's policies have been described at length in the Notices of Final Rulemaking. *See* Discussion at p. 17 of this brief, *infra*.

In addition to receiving or being given access to hundreds of thousands of pages of documents, Abbott has taken extensive oral discovery regarding CMS's administration of drug payments by both the Medicare and Medicaid programs. Abbott has deposed witnesses from every level in the CMS and OIG hierarchy, including former CMS administrators, about notices of proposed rulemaking, public responses thereto, and the articulation of final agency policies issued in the Federal Register. *See, e.g.,* Testimony of K. Buto, (former HCFA Associate Administrator for Policy) at 253-73 (testifying about regulation relating to 1992 physician fee schedules and CMS's official responses to public comment thereon)[6]; Testimony of N. DeParle, (former HCFA Administrator) at 242-57 (testifying about regulation relating to 1999 physician fee schedules and CMS's official responses to public comment thereon).[7]

With regard to the question that Abbott has repeatedly contended is "dispositive" in this case – why CMS continued to pay based on AWP "when officials knew there was a 'spread' between AWP and acquisition costs" – there has been abundant testimony on this issue. As demonstrated by the following exchange between Abbott's counsel and Thomas Gustafson

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[6] Exhibit 2 to Dkt. 4869.

[7] Exhibit 3 to Dkt. 4869.

(former Deputy Director, Center for Medicare Management, CMS), CMS used the AWPs from compendia due to a lack of other, readily available, sources for this data:

> [Counsel for Abbott]: Q. You believed it was reasonable to rely upon published average wholesale prices in Red Book as an accurate reflection of the average price that customers were paying for pharmaceutical products is that correct?
>
> [Objection by Government counsel to form]
>
> THE WITNESS: As a reasonably accurate representation. ***Had there been a readily available inexpensive more accurate data source I believe we would have used one as we began to do in 2000. We did not find any such source so we continued to rely on that which was readily available to us.***

Dkt. 5144-1, pp. 373-74.

By withholding a discrete set of privileged documents, the United States has not deprived defendants of factual information relating to what the Government knew about the real prices for their drugs or how the drug benefit was administered. Final versions of OIG's reports, as well as the final CMS comments on the reports and OIG's responses to CMS's comments have been publicly available since long before the commencement of discovery in this litigation. The United States has also produced non-privileged internal OIG work paper files for the OIG reports. Defendants have also extensively deposed high level witnesses from both CMS and OIG during the previous phase of discovery in this case.

In sum, if there were any open issue regarding the Government's intent behind the use of AWP to set payment amounts, there is abundant information available in the public record and in the non-privileged material produced in this case.

Factors Three and Four - Seriousness of the Issues and the Government's Role in Case

The United States recognizes that, if proven, Abbott's abuse of the system in place to determine payment amounts under Government healthcare programs is a serious matter because

of its impact on the resources devoted to providing healthcare to the poor and elderly and because it undermines the integrity of the systems used by the government and private entities to appropriately pay providers who dispense drugs. The Government does not concede, however, that the arguments made by Abbott to invade the deliberative process privilege can survive even facial scrutiny and be deemed "serious." Abbott says it requires access to internal agency documents to demonstrate that the *amicus* brief filed by the Government relating to the legal issue resolved by the Court's November 2006 summary judgement ruling contained factual misstatements and that the Government misled the Court. *See* Dkt. 4890 at 3-4. This Court, however, construed the term "AWP" based on its plain language, not on the basis of some unspecified factual assertion made in a brief of the United States. Abbott's argument regarding its purported need for the material is not serious.

Factor Five - Future Effect on Government Employees

As established by the declarations of the Government officials who asserted the deliberative process privilege here and as reflected in case law directly on point, the Government would be subject to real harm from the release of these materials. The Declaration of CMS Official Leslie Norwalk discusses the importance of candid internal discussion, deliberation, and analysis within CMS. *See* L. Norwalk Decl., ¶¶ 15-21 (Dkt. 4697-7). As this Court has recognized, the deliberative process privilege protects an important governmental interest because "the release of [deliberative] materials would discourage candid discussion within the agency and thereby undermine HHS's ability to perform effectively its assigned function. *See American Fed. of Govt. Employees.* 63 F.Supp. 2d 104, 108 (D. Mass. 1999). "Moreover, in addition to the chilling effect that disclosure could have on agency employees, the release of

incomplete, inaccurate or unsubstantiated information in [internal agency documents] could cause harm by providing the public with erroneous information...." *Id.* (citing *Providence Journal Co. v. United States Dep't of the Army*, 981 F.2d 552, 559 (1st Cir.1992).

Application of the Review Factors to Documents Submitted *In Camera*

As explained above, as a general matter, Abbott cannot establish any need for the Government's privileged documents given the allegations in this case, the Court's prior ruling on seminal issues, and the legal principles which determine the resolution of those issues. A review of the particular documents and groups of documents leads to the same conclusion.

1. Internal Agency Comments on Drafts of Final Rules

The documents from this category are from CMS's Rulemaking Support Files and consist of agency memoranda regarding final rules published in the federal register.[8] The document at Tab 1(A) consists of "Briefing Material" sent to the Policy Coordinator who worked in the Executive Secretariat in the Office of the Secretary (ES/OS). From the cover memorandum (HHD816-001) and attached pages, it is abundantly clear that the documents are both pre-decisional and deliberative. The document is being submitted for *in camera* review because, beginning at the middle paragraph on page HHD816-0021, it describes comments from oncologists who suggested that CMS's payment for chemotherapy drugs should cover costs associated with breakage, spoilage, inventory and other associated items - arguably a species of "subsidization." The next paragraph in the document describes steps which CMS proposed to use to analyze this issue. The document at Tab 1(B) sets out OIG's comments to the Executive

[8] The documents are behind Tabs 1(a) through 1(c) in the *in camera* submission and bear the Bates numbers HHD816-001 through 0028.

Secretariat and, beginning at the middle of page HHD816-0026 through the ensuing page, also addresses the breakage and inventory issues. The second paragraph on page HHD816-0028 (behind Tab 1(C)) also addresses this issue.

CMS addressed precisely the issue covered in each of the documents described above in the Notice of Final Rulemaking published in the Federal Register on November 25, 1991. With respect to "Drugs Furnished Incident to a Physician's Service," the agency stated: "In calculating estimated acquisition costs, indirect costs such as inventory, waste and spoilage may be considered." 56 Fed. Reg. 59,507. CMS's response to the commentary on breakage and spoilage is set out at 56 Fed. Reg. 59,525.

The Court should not order disclosure of the internal privileged documents. First, the non-public comments of agency staff are, per *United States. v. Lachman, supra*, irrelevant. Second, the agency's position on the matter addressed in the privileged documents is set out (and has been since 1991) in the Federal Register, and is therefore available from a source other than privileged material. Additionally, former high level CMS officials have been deposed about this rulemaking - such that there is another, non-privileged source for information on this issue. *See, e.g.* Deposition of former HCFA Associate Administrator for Policy, *supra*) (Dkt. 4869-2). Third, defendants can show no need for the privileged material in light of the content of the documents at issue. To the extent that defendants are seeking evidence that could undermine previous holdings and findings by the Court in this MDL, or the arguments made in any legal brief filed by the United States, the documents submitted at Tab 1 are useless to them.

2. Internal Agency Memoranda and Draft Correspondence Regarding Drug Payment Policies

The documents in this category are behind Tab 2(A) and 2(B) of the *in camera* submission and are from the Office of Legislation at CMS.

The documents behind Tab 2(A) were created in 2000 and consist of draft briefing documents addressed to Kevin Thurm, who, at that time, was the Deputy Secretary for DHHS and, as such, was the second-highest ranking official in the Department. The material relates to the proposal to allow Medicare carriers to use pricing information obtained by the Department of Justice (sometimes referred to within the industry as the "the DOJ prices") when determining payment amounts for certain drugs. The material is being submitted to the Court because the inhalation drug albuterol is mentioned in the documents.

The Court should not order disclosure of the documents behind Tab 2(A). First, the internal comments of agency staff are, per *United States v. Lachman*, irrelevant. Second, the agency's position on the matter addressed in the privileged documents was explicitly set out in a publicly- released Program Memorandum in 2000. *See* HCFA Prog. Mem. AB-00-86 (Sept. 8, 2000). Moreover, at this point, the defendants have devoted many hours, indeed even days, of deposition time with senior CMS officials to the subject of the so-called "DOJ prices." Third, defendants can show no need for the privileged material in light of its content. Again, CMS's authorization of the use of DOJ pricing information is entirely consistent with the Court's findings *In Re Average Wholesale Price Litig.,* 491 F. Supp. 2d at 39-45, regarding the agency's struggle to respond to the evidence which developed over time concerning the abusive price reporting practices of some manufacturers and certain pharmaceutical products. Nothing in the

documents submitted *in camera* tend support Abbott's central argument in this case - that mega-spreads were somehow consistent with the agency's payment objectives and policies.

The documents at Tab 2(B) are copies of draft versions of a letter to Congressman Tom Bliley.[9] The final version of this letter was produced by the United States. The draft copy contains hand-written marginalia regarding the phrasing of the letter and was created in 2000. The document discusses the issue of Medicare's use of AWP pricing information obtained by DOJ for payment purposes. The document is being submitted for *in camera* review because information on page HHD980-0138 indicates that there was an AWP spread for the inhalant drug albuterol sulfate. There is no reason the Court should order production of this draft document. The United States has produced the final version of the correspondence. Nothing in the text of the draft, as in the final version, supports Abbott's argument that inflated payment amounts were somehow viewed as accomplishing legitimate payment policies or objectives.

The documents behind Tab 2(C) are draft memoranda from 2003 and are, therefore, of very little relevance to any legitimate issue in this case given that, in this time frame, the Government's interest in, and efforts toward, changing drug payment methodologies was reaching a mature state culminating in an extensive revamping of Medicare's drug payment system. Also, these documents were created after the claims period in the Abbott case, which runs only though 2001. The documents are being submitted for *in camera* review because they reference the existence of AWP spreads. *See, e.g.,* HHD811-0043. The documents were prepared by the Office of Legislation and discuss options that were being considered prior to

[9] The documents bear the Bates numbers HHD980-0137 through 140 and HHD976-0269 through 271.

passage of the MMA. The documents, on their face, are plainly core deliberative process material. There is nothing in the documents that is of any use to defendants.

The document at Tab 2(D) is dated January 9, 2003, and is a confidential memorandum from a Consultant in CMS's Planning and Policy Analysis Group to the Director of CMS's Office of Research, Development and Information and the Director of CMS's Planning Policy Analysis Group. The memorandum reviews and critiques various options that CMS was considering to address the "problem" of AWP inflation. The document, on its face, is core deliberative process material. Nothing in the text of the document supports Abbott's arguments regarding the policy objectives associated with the use of published AWPs.

The document at Tab 2(E) is a copy of a 1998 email from an official in the Office of Legislation regarding a draft regulation. (HHD816-0029). The email discusses a potential revision to language in the preamble of the draft regulation and whether physician practice expenses associated with administering cancer drugs should be treated separately from the costs of the drugs themselves. Per *United States v. Lachman*, the agency's final position on this issue is articulated when the agency issues a final rule. In any event, there is nothing in the text of the email that provides any support for any defendant's cross-subsidization argument.

The document at Tab 2(F) is an internal CMS email that was circulated among high level agency officials (HHC902-0080). The email indicates that the author expected to be contacted by a television news reporter regarding an "expose" on nebulizer drugs. The only information in the email regarding the spread between the cost of drugs and Medicare's payment amount is that which was developed by the news organization involved in the expose. Nothing in the document

can be used to support defendants' arguments regarding CMS's policy objectives associated with the use of published AWPs.

3. OIG Memoranda

The document behind Tab 3(A) of the Government's *in camera* submission is a December 2001 memorandum from the OIG to the Deputy Secretary of HHS regarding the inflated nature of published wholesale prices that contains OIG recommendations on the issue. The memorandum for the most part summarizes information developed in various reports on which OIG had been working during 2001 and attached copies of most of those reports. *See* HHD929-0007. The underlying reports have all been publicly available since they were issued. The summary document behind Tab 3(A) is of no value to defendants.

The document at Tab 3(B) is a draft memo from the CMS Administrator to the Inspector General of DHHS relating to a 2001 OIG draft report.[10] Final versions of CMS's responses to the findings and recommendations in the OIG's responses are appended to the final copies of the OIG reports. The draft document references the findings by the OIG regarding significant differences between actual drug acquisition costs of generic drugs and AWP. The draft document does not contain any information or evidence that cannot be readily obtained from the publicly available final versions of the CMS memorandum and OIG report.

4. Draft Memo by Carrier Medical Director

Behind Tab 4 is a cover memorandum attaching a draft memo which a medical director employed by a Durable Medical Equipment Regional Carrier (DMERC) had prepared and was considering sending to CMS's Bureau of Policy Development (BPD) in 1995. (HHD919-0022-

[10] The document bears the Bates number HHD978-0432 through 433.

24) The first full indented paragraph of the draft memorandum references the difference between invoiced prices for albuterol and payment amounts determined by the DMERC. The draft memorandum considers approaches to addressing this situation. A draft memorandum from a Medicare contractor does not establish policy for the agency. Accordingly, defendants cannot establish any conceivable need for the document.

Abbott has no need for any of the documents submitted *in camera* to the Court. The documents are irrelevant to any issue which is truly implicated in this case. The Court has already resolved the key issue of interest to Abbott by virtue of its November 2006 Order in which it construed the term AWP pursuant to its plain language. Moreover, even if there was an open issue regarding Governmental intent and this pricing term, it would be resolved by reference to public policy pronouncements by CMS. The only documents from CMS which could possibly be relevant to defendants' scienter are those which were publicly available during the claims periods in the cases brought by the United States. Finally, given that the documents are irrelevant, the potential chilling effect that the release of such documents would have on agency officials and the accomplishment of CMS's mission plainly outweighs defendants' interest in their disclosure.

Conclusion

Based on the foregoing, the United States respectfully requests that the Court not require the United States to produce the documents submitted *in camera* concurrently with this memorandum, and that the Court deny Abbott's request to pursue an interlocutory appeal of the Court's holdings regarding the deliberative process privilege.

Respectfully submitted,

For the United States of America,

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Dated: September 15, 2008.

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "MEMORANDUM BY THE UNITED STATES RELATING TO THE IN CAMERA SUBMISSION OF DOCUMENTS FOLLOWING THE HEARING ON JULY 24, 2008 to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Justin Draycott
Justin Draycott

Dated: September 15, 2008